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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,349	08/19/2003	Robert Seid	2300-1357.10 (PP01357.124)	3803
27476	7590	09/29/2005	EXAMINER	
Chiron Corporation Intellectual Property - R440 P.O. Box 8097 Emeryville, CA 94662-8097			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,349

Applicant(s)

SEID, ROBERT

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,32,43,45-47 and 50-55 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,32,43,45-47 and 50-55 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Applicant's Amendment

Applicant's Amendment

- 1) Acknowledgment is made of Applicant's amendment filed 06/13/05 in response to the non-final Office Action mailed 03/23/05.

Status of Claims

- 2) Claim 44 has been canceled via the amendment filed 06/13/05.
Claims 31, 32 and 43 have been amended via the amendment filed 06/13/05.
New claims 50-55 have been added via the amendment filed 06/13/05.
Claims 31, 32, 43, 45-47 and 50-55 are pending and are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Moot

- 5) The rejection of claim 44 made in paragraph 8 of the Office Action mailed 09/30/04 and maintained in paragraph 12 of the Office Action mailed 03/26/05 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of the U.S. Patent 6,638,513, is moot in light of Applicant's cancellation of the claim.
- 6) The rejection of claim 44 made in paragraph 24(f) of the Office Action mailed 03/26/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicant's cancellation of the claim.
- 7) The rejection of claim 44 made in paragraph 25 of the Office Action mailed 03/26/05 under 35 U.S.C. § 103(a) as being unpatentable over Jennings *et al.* (US 5,811,102 - Applicants' IDS) ('102) in view of Sato *et al.* (*J. Biol. Chem.* 270 (32): 18923-18928, 1995 - Applicant's IDS) and

Staveski *et al.* (US 5,354,853 - Applicant's IDS), is moot in light of Applicant's cancellation of the claim.

Rejection(s) Withdrawn

8) The rejection of claims 31 and 32 made in paragraph 24(c) of the Office Action mailed 03/26/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claims.

9) The rejection of claims 31 and 32 made in paragraph 24(d) of the Office Action mailed 03/26/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claims.

10) The rejection of claim 43 made in paragraph 24(e) of the Office Action mailed 03/26/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

11) The rejection of claims 31, 32, 43 and 45-47 made in paragraph 25 of the Office Action mailed 03/26/05 under 35 U.S.C. § 103(a) as being unpatentable over Jennings *et al.* (US 5,811,102 - Applicants' IDS) ('102) in view of Sato *et al.* (*J. Biol. Chem.* 270 (32): 18923-18928, 1995 - Applicant's IDS) and Staveski *et al.* (US 5,354,853 - Applicant's IDS), is withdrawn upon further consideration.

Rejection(s) Maintained

12) The rejection of claims 31, 32, 43 and 45-47 made in paragraph 8 of the Office Action mailed 09/30/04 and maintained in paragraph 12 of the Office Action mailed 03/26/05 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of the U.S. Patent 6,638,513, is maintained for reasons set forth therein and herebelow. Applicant requests that the requirement for submission of a Terminal Disclaimer be held in abeyance until there is an indication of allowable subject matter in the present application.

New claims 50-55 are now included in this rejection.

13) The rejection of claim 31 and those that are dependent therefrom made in paragraph 23 of the Office Action mailed 03/26/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is maintained for reasons set forth therein and herebelow.

Applicant cites case law and contends that limiting the invention to the propionyl derivative depicted in the figures and described in the examples of the specification would improperly limit the claims to the preferred embodiment. Applicant submits that the preparation of the N-propionyl derivative is merely described as a preferred embodiment, and not as the only embodiment. Applicant states that claim 31 has now been amended to include the steps of 'providing a heterogenous population of *Neisseria meningitidis* serogroup B capsular oligosaccharide (MenB OS) in which sialic acid residue N-acetyl groups are replaced with N-C₃-C₈ acyl groups' and 'covalently attaching the single end-activated MenB OS to a protein carrier molecule'. Applicant points to lines 1-11 at page 8, lines 1-7 at page 11, lines 26-34 at page 13, and lines 1-22 of page 16 of the specification as providing descriptive support for the amendments to the claim.

Applicant's arguments have been carefully considered, but are not persuasive. It should be noted that the method of producing the glycoconjugate that is described in the instant specification involves replacement of sialic acid residue N-acetyl groups specifically with N-propionyl groups. The method described herein lacks the instantly recited step (c), i.e., covalently attaching a C₃-C₁₆ long-chain aliphatic lipid to the nonreducing end of the MenB OS obtained in step (b)'. As set forth previously, page 14, line 16 through page 16, line 33 of the instant specification describe methods of preparing glycoconjugates with covalently attached lipids. A further review of the specification indicates that these portions of the specification are limited to a specific MenB OS glycoconjugate, 'CONJ-4', comprising substantially homogeneous sized N-propionylated MenB OS having a C₃-C₁₆ long-chain aliphatic lipid covalently attached to the non-reducing end of the N-propionylated MenB OS and being conjugated to a protein carrier. These portions of the specification do not describe a glycoconjugate as recited in the amended claim 31 comprising MenB OS having N-acetyl groups replaced with 'N-C₃-C₈ acyl groups', as recited currently. The scope of the limitation, 'N-C₃-C₈ acyl groups', is not the same as the scope of the limitation, 'N-propionyl groups'. The rejection stands.

14) The rejection of claim 31 made in paragraph 24(a) of the Office Action mailed 03/26/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

Applicant states that claim 31 has been amended as suggested by the Office to replace the

limitation in line 1 with 'a substantially homogenous sized *Neisseria meningitidis* serogroup B capsular oligosaccharide (MenB OS) produced by a method'. However, claim 31, as amended, does not contain such a limitation in line 1 of the claim. The rejection stands.

15) The rejection of claim 32 made in paragraph 24(b) of the Office Action mailed 03/26/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

Applicant asserts that claim 32 has been amended similarly to claim 31. However, the amendment to claim 32 does not address the issue raised in paragraph 24(b) of the Office Action mailed 03/26/05. The rejection stands.

16) The rejection of claims 43 and 45-47 made in paragraph 24(f) of the Office Action mailed 03/26/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and *supra*.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

17) Claims 31, 32, 43, 45-47 and 51-55 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claims 31 and 32, as amended, have improper antecedent basis in the limitation: 'the substantially homogenous sized MenB OS/CRM₁₉₇ toxoid glycoconjugate' (see last two lines), because there is no earlier recitation of 'a substantially homogenous sized MenB OS/CRM₁₉₇ toxoid glycoconjugate' in the claim.

(b) Analogous criticism applies to new claim 50.

(c) Claim 32 is confusing and internally inconsistent in the limitation, because the first two lines of the claim indicates that the glycoconjugate produced by the recited method is 'A *Neisseria meningitidis* serogroup B capsular oligosaccharide (MenB OS) glycoconjugate'. However, the product obtained at the end of step (e) of the method is recited to be 'the substantially homogenous sized MenB OS/CRM₁₉₇ toxoid glycoconjugate'. The two glycoconjugate products are not of same scope.

(d) In step (d) of claims 31 and 32, for proper antecedent basis, it is suggested that Applicant replace the limitation: 'single end-activated MenB OS' with the limitation --single

end-activated MenB OS of said Dp--.

(e) In line 7 of claim 31, line 8 of claim 32, and line 6 of claim 50, for clarity and/or consistency, it is suggested that Applicant replace the limitation 'of (a)' with --of step (a)--.

(f) For clarity, it is suggested that Applicant replace the limitation: 'the single end-activated MenB OS' in line 13 of claim 31, and line 14 of claim 32, with --the single end-activated MenB OS obtained in step (d)--.

(g) Analogous criticism applies to new claim 50.

(h) Claims 46 and 53, which depend from claim 45 and claim 52 respectively, are not properly further limiting. It is suggested that Applicant replace the limitation 'wherein the carrier molecule is a nontoxic mutant bacterial toxoid' with the limitation wherein the bacterial toxoid is a nontoxic mutant bacterial toxoid--.

(i) Claims 45 and 46 are indefinite and incorrect in their direct or indirect dependency from the canceled claim 44.

(j) For proper antecedence, in line 1 of claim 52, it is suggested that Applicant replace the limitation 'the carrier molecule' with the limitation --the protein carrier molecule--.

(k) Claim 54 is vague and confusing in the limitation: 'a CRM₁₉₇ carrier molecule'. For the purpose of distinctly claiming the subject matter, it is suggested that Applicant replace the limitation with --CRM₁₉₇--.

(h) Claims 43, 45-47 and 51-55, which depend directly or indirectly from claim 31 or claim 50, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 103

18) Claims 50-55 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jennings *et al.* (US 5,576,002 - already of record) ('002) or Jennings *et al.* (US 5,902,586 - already of record) ('586) in view of Kitazume *et al.* (*Anal. Biochem.* 202: 25-34, 1992 - already of record) or Jennings *et al.* (*J. Immunol.* 134: 2651-2657, 1985 - already of record) and Kniskern *et al.* (US 5,847,112, filed in 1991 - already of record), Marburg *et al.* (US 5,623,057 - already of record) and Jennings *et al.* (US 5,811,102 - already of record) ('102).

The references of Jennings *et al.* ('586) and Marburg *et al.* in this rejection are applied

because they qualify as prior art under subsection (e) of 35 U.S.C. § 102 and accordingly are not disqualified under U.S.C. 103(a).

Jennings *et al.* ('002) taught glycoconjugate vaccines of *N*-propionylated derivatives of serogroup B *Neisseria meningitidis* capsular polysaccharide fragments (i.e., MenB OS) conjugated to a protein carrier by reductive amination or other methods of conjugation using adipic dihydrazide spacer. The immunogenic carrier protein that is used is tetanus toxoid or CRM₁₉₇ (i.e., a nontoxic mutant bacterial toxoid). See abstract and column 4, lines 34-36 and last paragraph. The conjugate is present in an adjuvant (i.e., a pharmaceutically acceptable carrier). The serogroup B meningococcal polysaccharide derivative is fragmented (i.e., converted to oligosaccharides) to have an average molecular weight of 10,000 to 15,000 Daltons or about 30 to 200 sialic acid residues. The polysaccharide fractions are obtained by gel filtration (see column 4, lines 18-34 and column 6, lines 19-35). The glycoconjugates comprise *N*-propionyl derivatives of group B meningococcal capsular polysaccharide fragments. The *N*-propionyl fragments are produced from the *N*-deacetylated fragments. Terminal aldehyde groups are introduced into the *N*-propionylated serogroup B meningococcal capsular polysaccharide fragments by periodate oxidation, which are then conjugated to a protein carrier. See column 6, last paragraph; and 'Materials and Methods for Preparing Conjugates'. The replacing group is *N*-C₄-C₈ acyl group (see claims and Table 4).

Jennings *et al.* ('586) teach serogroup B *Neisseria meningitidis* capsular glycoconjugates that induce protective antibodies with negligible levels of GBMP-cross reactive antibodies (see abstract). The glycoconjugate containing the *N*-propionylated GBMP polysaccharide fragment conjugated to tetanus toxoid or CRM197 shows enhanced immunogenicity with substantially reduced inducement of cross-reactive antibodies and enhanced inducement of *N*-Pr-GBMP-specific bactericidal antibodies (see column 2, lines 10-29; column 4, lines 41-43; and Table 5). See also 'Materials and Methods for Preparing Conjugates'. The average molecular weight of the PS fragment corresponds to about 30 to 200 sialic acid residues and is obtained by ultragel filtration (see column 4, lines 16-27). The processes of *N*-deacetylation, *N*-acylation including *N*-propionylation, and sizing of the fragments of the PS derivatives are taught by way of Examples (see columns 5 and 6). It is taught that *N*-acylated MenB oligosaccharides of 'desired' average

molecular weight can be obtained by ultragel filtration (see column 6, second paragraph). The conjugate is produced via reductive amination using adipic dihydrazide spacer (see column 4, last paragraph and column 4, lines 41-43). The resultant N-acylated or N-propionylated glycoconjugates have improved immunogenicity, do not possess significant cross-linking, are soluble in aqueous solutions and are good candidates for vaccine use (see column 5, lines 5-13 and 35-39). The replacing group is N-C₄-C₈ acyl group (see claims and Table 4).

Jennings *et al.* ('002 or '586) do not refer to the size of serogroup B meningococcal capsular oligosaccharides as substantially homogeneous sized or in terms of degree of polymerization or homogeneity as recited.

However, the isolation of serogroup B meningococcal capsular oligosaccharides having an average DP of 10 to 20, or 12 to 18, and their advantageous use in a conjugate was well known in the art at the time of the invention. For instance, Jennings *et al.* (1985) taught the isolation of serogroup B meningococcal capsular oligosaccharides of various defined chain lengths including 12 to 18 residue-long, and 10-20 residue-long oligosaccharides (see pages 2652 and 2653 and Figure 1).

Similarly, Kitazume *et al.* taught the isolation of oligosaccharides of alpha(2->8) polysialic acid. Kitazume *et al.* taught a method of obtaining homooligomers of alpha(2->8) polysialic acid or colominic acid having a DP of 1 to 14 and 1 to 10 by partial acid hydrolysis of colominic acid followed by chromatography (see entire document).

The use of such capsular oligosaccharides of serogroup B *Neisseria meningitidis* of reduced size in a glycoconjugate vaccine was expressly taught in the prior art at the time of the invention. For example, Kniskern *et al.* taught glycoconjugates comprising a bacterial capsular polysaccharide having an average of less than about 1000 oligosaccharide repeat units per molecule (see abstract). The polysaccharide is size-reduced by thermal, physical, chemical or enzymatic treatment and treated to decrease the polydispersity. A method of decreasing the polydispersity of the glycoconjugate is taught (see claims). Kniskern *et al.* identified the non-homogeneous nature of the bacterial polysaccharide starting material as a major problem in the production of conjugates. Kniskern *et al.* identified the need in the art for a process wherein well defined starting polysaccharide materials are produced that are amenable to conjugation (see first

full paragraph in column 2). Kniskern's improvements include preparation of a bacterial polysaccharide starting material having more specific, reproducible and manageable physical properties, such as, increased solubility, increased filterability, increased purity, reduced molecular weight, reduced polydispersity and reduced viscosity (see third full paragraph in column 2). The reduced size allows for improved polysaccharide handling during conjugation and post-conjugation removal of non-conjugated polysaccharide and essentially unaltered antigenicity. These novel polysaccharide characteristics are used advantageously in the consistent formation of highly chemically defined, more homogeneous, highly type-specific, antigenic polysaccharide conjugates of enhanced immunogenicity (see lines 38-59 on column 4). Kniskern *et al.* expressly taught that conjugates of these properties can be produced using the polysaccharide of "*Neisseria meningitidis* B" (see first full paragraph in column 14).

Similarly, Marburg *et al.* disclosed chemically defined bacterial capsular oligosaccharide glycoconjugates comprising hydrolyzed oligosaccharides of reduced molecular size, reduced polydispersity, and reduced viscosity (see column 2 last paragraph and column 3). These glycoconjugates are significantly improved products compared to the previously available products, the improvements being greater chemical definition, increased consistency, increased ease of manufacture, retention of T-cell dependency and high degree of covalency (see column 3). The oligosaccharide used may be derived from serogroup B *Neisseria meningitidis* capsular polysaccharide (see column 4, lines 42-46). Marburg *et al.* taught the advantages of using reduced sized polysaccharides in a bacterial capsular glycoconjugate by stating that the reduced size allows for improved polysaccharide handling during conjugation and post-conjugation removal of free polysaccharide, higher purity/homogeneity, lower molecular size polydispersity and essentially unaltered antigenicity of the polysaccharide, which characteristics contribute significantly to the consistent formation of a highly defined and highly antigenic products (see column 5, lines 1-8). Methods of obtaining homogenous or monodisperse hydrolyzed polysaccharide preparations (see column 5) and determination of average molecular weight and the average number of repeating units per molecule are taught (see the paragraph bridging columns 5 and 6). A method of providing a polydisperse or heterogeneous bacterial polysaccharide derivative and obtaining a monodisperse or homogenous preparation of the desired molecular weight or chain length (see column 16) and a

method of size reducing the polysaccharide to a consistent target endpoint without altering its antigenic characteristics (see column 15, lines 40-45) are taught.

Given the identified the need in the art for glycoconjugate vaccines containing well defined starting polysaccharide materials that are amenable to conjugation as taught by Kniskern *et al.*, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention to replace Jennings' ('002 or '586) serogroup B *Neisseria meningitidis* capsular polysaccharide fragments with Jennings' (1985) homogeneous 12 to 18 residue-long or 10-20 residue-long serogroup B *Neisseria meningitidis* capsular oligosaccharides, or Kitazume's serogroup B *Neisseria meningitidis* capsular oligosaccharides of 12 Dp, to produce the glycoconjugate of the instant invention, with a reasonable expectation of success, because: a) Kniskern *et al.* expressly taught that oligosaccharide conjugates of increased solubility, increased filterability, increased purity, reduced molecular weight, reduced polydispersity, and reduced viscosity can be produced using the polysaccharide of *Neisseria meningitidis* B; or b) Marburg *et al.* expressly taught that significantly improved, consistent and chemically defined, T-cell dependent glycoconjugates of high degree of covalency comprising oligosaccharides of reduced molecular size, reduced polydispersity, and reduced viscosity may be derived from serogroup B *Neisseria meningitidis* capsular polysaccharide. One of ordinary skill in the art would have been motivated to produce the N-propionylated serogroup B meningococcal capsular oligosaccharide glycoconjugate comprising oligosaccharides of reduced homogeneous size of Dp 10-20, 12-18, or Dp 12 for the expected benefit of accomplishing: a) improved polysaccharide handling during conjugation and post-conjugation removal of free polysaccharide, higher purity/homogeneity, lower molecular size polydispersity and essentially unaltered antigenicity of the polysaccharide, all characteristics that contribute significantly to the consistent formation of a highly defined and highly antigenic glycoconjugate product as taught by Marburg *et al.*; or b) advantageously consistent formation of highly chemically defined, more homogeneous, highly specific, antigenic conjugates of enhanced immunogenicity as taught by Kniskern *et al.*

Claims 50-55 are *prima facie* obvious over the prior art of record.

Relevant Art

- 19) The art made of record is considered pertinent to Applicant's disclosure:

- Granoff (US 6,413,520) discloses glycoconjugates of group B meningococcal capsular polysaccharide (see entire document).

Remarks

- 20)** Claims 31, 32, 43, 45-47 and 50-55 stand rejected.
- 21)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (571) 273-8300.
- 22)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
- 23)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

August, 2005


S. DEVI, PH.D.
PRIMARY EXAMINER